June 27, 2019

VIA UPS EXPRESS

Susan B. McCoy
Executive Director
Mississippi Board of Pharmacy
6360 I-55 North
Suite 400
Jackson, Mississippi 39211

Ms. McCoy:

The purpose of this letter is to refer to the Mississippi Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy licensed by the Mississippi BOP, Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc., located at 240 S. 13th Avenue, Laurel, Mississippi 39440-4226 (Pharmacy License #01098 Exp. 12/31/19; Controlled Substance License #CS-01098 Exp. 12/31/19).

FDA inspected the firm from November 26, 2018, to November 29, 2018. The FDA investigator was accompanied by a Mississippi state investigator during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/122501/download, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. As a Commissioned Official, or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc. and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

During the inspection, the FDA investigator observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm produced hazardous drug products without providing adequate containment, segregation, and cleaning of work surfaces and utensils to prevent cross-contamination.

2. Personnel engaged in aseptic processing were observed not changing their gloves frequently enough during production to prevent contamination.

Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc. committed to FDA in its response to the Form FDA 483, received on December 19, 2018, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Mississippi State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Jose R. Lopez, Compliance Officer, at (787) 729-8603, or by email at JoseR.Lopez@fda.hhs.gov.

Sincerely,

John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
Date: 2019.06.27 11:33:15 -05'00'

CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Kenneth E. Crawford III
Owner and Pharmacist in Charge
Crawford's Professional Drugs, Inc. dba Diket's Professional Drugs, Inc.
240 S. 13th Avenue
Laurel, Mississippi 39440-4226